

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCT)
LIABILITY LITIGATION)**
_____)

**MDL No. 2419
Dkt. No 1:13-md-2419 (FDS)**

**THIS DOCUMENT RELATES TO:)
)
All Actions)**
_____)

**THOREK MEMORIAL HOSPITAL'S OBJECTIONS TO AND MOTION TO QUASH
THE PLAINTIFFS' STEERING COMMITTEE'S REVISED SUBPOENA EXHIBIT**

NOW COMES Thorek Memorial Hospital ("Thorek"), and submits its Objections to Plaintiff's Steering Committee's ("PSC") revised subpoena exhibit, which requests the production of voluminous documents and records. PSC's revised subpoena exhibit should be quashed or modified, pursuant to Federal Rules of Civil Procedure 45 and 26, for the following reasons:

- The United States District Court for the District of Massachusetts does not have jurisdiction over Thorek;
- The requests made in the revised subpoena exhibit (Doc # 470) are overly broad, unduly burdensome, and not calculated to lead to relevant and admissible evidence;
- The revised subpoena exhibit violates HIPAA and Illinois privacy laws;
- The revised subpoena exhibit exceeds the scope of the limited discovery approved by the court; and
- The revised subpoena exhibit creates an undue burden and seeks irrelevant information in violation of Federal Rules of Civil Procedure 26(b) and 45.

BACKGROUND

On September 30, 2013, PSC served a revised exhibit to its subpoena, requesting voluminous records and documents. The revised subpoena exhibit was issued from the United States District Court for the District of Massachusetts and signed by Kimberly A. Dougherty.

STANDARD OF REVIEW

The Court, under its MDL authority, has the power to issue foreign-district subpoenas pursuant to 28 U.S.C. § 1407(b). *United States ex rel. Pogue v. Diabetes Treatment Centers of America, Inc.*, 444 F.3d 462, 468 (6th Cir. 2006). However, when a court exercises its 28 U.S.C. § 1407(b) authority to issue a subpoena to a foreign-district nonparty deponent, the MDL judge sits as a judge of the district court where the deponent resides. *Id.* In addition, because the MDL judge is acting as a judge of the deponent's district, appeal is to the circuit court of the deponent's district. *Id.* At 469. In regard to the subpoena issued to Thorek, the Honorable Judge Saylor sits as a judge of the United States District Court for the Northern District of Illinois and is bound by the precedent of the United States Seventh Circuit Court of Appeals.

ARGUMENT

I. THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS DOES NOT HAVE JURISDICTION OVER THOREK MEMORIAL HOSPITAL

Thorek is located at 850 W. Irving Park Road, Chicago, IL 60613 and sits within the jurisdiction of the United States District Court for the Northern District of Illinois. Therefore, the United States District Court for the District of Massachusetts does not have jurisdictional authority over Thorek.

II. THE PRODUCTION REQUESTS VIOLATE THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT ("HIPAA") AND ILLINOIS PRIVACY LAWS

A district court must quash or modify a subpoena if it "requires disclosure of privileged or otherwise protected matter and no exception or waiver applies." *Fed. R. Civ. P. 45(c)(3)(A)(iii)*; *Abbott v. Kidder, Peabody & Co.*, 1997 U.S. Dist. LEXIS 8500, 1997 WL 337228, *2 (N.D. Ill. 1997). The records sought by PSC cannot be released under Illinois law, which provides for strict disclosure protections under the physician-patient privilege, and are therefore protected under HIPAA.

HIPAA allows a hospital such as Thorek to disclose patient medical records subject to a court order. *45 C.F.R. § 164.512(e)(1)(i)*. HIPAA does limit the authority of a court by requiring that the order:

prohibit[] the parties from using or disclosing the protected health information for any purpose other than the litigation and proceeding for which such information was requested [and] requires the return . . . or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.

45 C.F.R. § 164.512(e)(1)(v). In other words, HIPAA's regulations clearly allow a hospital to disclose patient medical records, when ordered in judicial proceedings, subject to the above limitations. However, Illinois law concerning when nonparty patient medical records may be disclosed by hospitals or doctors is far more restrictive. The Illinois Code of Civil Procedure states that "no physician or surgeon shall be permitted to disclose any information he or she may have acquired in attending any patient in a professional character, necessary to enable him or her professionally to serve the patient unless one of eleven numerated conditions exist. 735 ILCS 5/8-802. This medical privacy protection extends to hospitals that possess nonparty patient medical records. *Parkson v. Central DuPage Hospital*, 105 Ill. App. 3d 850, 435 N.E.2d 140, 142, 61 Ill. Dec. 651 (Ill. App. Ct. 1982). Unless one of these conditions is satisfied, absent the

patients' consent, a hospital may not disclose a patients' medical records, even in response to a subpoena. *People v. Manos*, 761 N.E.2d 208, 216-17, 326 Ill. App. 3d 698, 260 Ill. Dec. 364 (Ill. App. Ct. 2001) (citing *People v. Bickham*, 89 Ill.2d 1, 6, 431 N.E.2d 365, 59 Ill. Dec. 80 (Ill. 1982)).

The application of Illinois' medical privacy laws is not an "obstacle" to achieving Congress' aims in enacting HIPAA, but rather appears to be Congress' desired outcome under a statute that contemplates that state medical privacy laws supersede less protective federal regulations. *Nat'l Abortion Fed'n v. Ashcroft*, 2004 U.S. Dist. LEXIS 1701, 15-17 (N.D. Ill. Feb. 5, 2004). Because HIPAA governs how individually identifiable health information, such as medical records, should be kept private, Illinois law controls.

PSC's revised subpoena exhibit requests prescriptions submitted to NECP and prescription order forms (Revised Subpoena Exhibit Nos. 1, 3, 4). This information, and other information sought in the requests, relates to patient data. As such, the requests are invalid under HIPAA and Illinois privacy laws.

III. PSC HAS BREACHED THE COURT'S LIMITATION OF DISCOVERY

A. PSC's Breach of January, 2011 – November, 2012

On June 21, 2013, the Court entered an Order entitled, "Order Granting Plaintiffs Leave to Service Subpoenas and Qualified Protective Order Regarding Protection of Health Information" ("QPO"). The QPO provides as follows:

The information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions, medications or compounds from January, 2011 — November, 2012, the patients' last known address, the records identifying that NECC was the supplier of the solution, medication or compound, including lot number, the hospital or healthcare facilities' NECC product purchase records, including order forms, prescriptions, billing and accounts receivable, the hospital or healthcare facilities' NECC product storage and patient distribution

records, and any other information that lead counsel and the PSC reasonably determine necessary to the prosecution and resolution of these actions.

Dkt. No. 192 ¶ 2. PSC has requested documents outside the January, 2011 — November, 2012 timeframe, and seeks documents dating back as far as October 6, 2010. See Requests ¶¶ 2; 7; and 18 in Doc. # 470.

B. PSC Did Not Append the QPO to the Subpoenas

The Court ruled that its QPO “shall be appended to the subpoenas.” *See* Dkt. No. 192.

However, PSC failed to append the QPO to the subpoena served on Thorek.

IV. PLAINTIFFS’ REVISED SUBPOENA EXHIBIT PLACES AN UNDUE BURDEN ON THOREK, AND THE HARM AND BURDEN IMPOSED OUTWEIGHS THE POTENTIAL NEED AND RELEVANCE OF THE DOCUMENTS, ELECTRONICALLY STORED INFORMATION, AND TANGIBLE THINGS REQUESTED

Federal Rule of Civil Procedure 45 governs subpoenas. In relevant part, it states:

[o]n timely motion, the issuing court must quash or modify a subpoena that: (i) fails to allow a reasonable time to comply; (ii) requires a person who is neither a party nor a party’s officer to travel more than 100 miles from where that person resides, is employed or regularly transacts business in person . . . ; (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or (iv) subjects a person to undue burden. Fed. R. Civ. P. 45(c)(3)(A).

District courts have the discretion to grant, deny or modify a motion to quash a subpoena.

See Griffin v. Foley, 542 F.3d 209, 223 (7th Cir. 2008). A party seeking to quash a subpoena bears the burden of demonstrating that the subpoena requires the disclosure of privileged information or subjects the party to an undue burden. *AF Holdings LLC v. Doe*, No. 12 C 4222, 2012 U.S. Dist. LEXIS 162487, 2012 WL 5520861, *1 (N.D. Ill. Nov. 13, 2012). When analyzing whether a burden is “undue”, the Seventh Circuit employs a relative hardship test. *See Northwestern Mem. Hosp. v. Ashcroft*, 362 F.3d 923, 927 (7th Cir. 2004). This test takes into account a number of factors, including whether: (1) the party subpoenaed is a nonparty in the

underlying suit; (2) the information requested is relevant; (3) the party requesting the information has a substantial need for the documents; (4) the document request is overly broad; (5) the time period the request covers is reasonable; (6) the request is sufficiently particular; and (7) the request imposes a burden. See *Wi-Lan v. LG Electronics, Inc. et al.*, No. 10-CV-7721, 2011 U.S. Dist. LEXIS 4606, 2011 WL 148058 at *2 (N.D. Ill. Jan. 18, 2011).

In determining whether material sought in a subpoena is relevant, Rule 26 instructs “[r]elevant information need not be admissible at trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.” Fed. R. Civ. P. 26(b)(1). In light of this instruction, “[r]elevancy has been construed broadly to encompass any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case.” *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351, 98 S. Ct. 2380, 57 L. Ed. 2d 253 (1978). It is worth noting, however, that nonparties “are not treated exactly like parties in the discovery context, and the possibility of mere relevance may not be enough; rather, nonparties are entitled to somewhat greater protection.” *Patterson v. Burge*, No. 03-C-4433, 2005 U.S. Dist. LEXIS 1331, 2005 WL 43240 at *1 (N.D. Ill. Jan. 6, 2005).

Here, the potential relevance of and need for the documents requested in the revised subpoena exhibit are outweighed by the interest of confidentiality and the potential harm posed by the requests. To be sure, the requests are unduly burdensome, irrelevant, and not calculated to lead to admissible discovery.

First, it is undisputed that Thorek is a nonparty to this underlying litigation. As previously mentioned, this is one factor the Court considers in determining whether an alleged burden is undue in the relative hardship test. See *Wi-Lan*, 2011 U.S. Dist. LEXIS 4606, 2011 WL 148058 at *2. As a nonparty, Thorek does not have any documents that are relevant to the MDL or any

protected health records of Plaintiffs. Furthermore, there has been no indication that any plaintiff in the MDL was a patient at Thorek during the relevant time period and, therefore, any documentation requested of Thorek would be irrelevant.

Second, the overwhelming majority of documents requested can be produced by NECP, an actual party to the MDL. (Revised Subpoena Exhibit Nos. 12 and 13). The fact that NECP's bankruptcy case and federal investigation may somehow delay Plaintiffs' discovery from NECP is no reason to burden an Illinois entity who is not a party to this litigation.

Third, there is no need for many of the documents sought. The requests seek a myriad of information beyond information about patients who may have received the steroid injections at issue. Instead, the requests seek documents, electronically stored information, and tangible things related to the purchase of medications from NECP and other suppliers, the administration of products purchased from NECP other than the steroid medications, all communications between Thorek and NECP (without specifying a subject matter), and information from governmental entities. (Revised Subpoena Exhibit Nos. 1-18). Indeed, the document requests are prohibitively overbroad, seeking wholesale categories of documents, electronically stored information, and tangible things that have no bearing on the matters at issue in the MDL without any meaningful limitation or other attempt to connect the requests to any fact of consequence.

Fourth, the documents are broadly requested. Plaintiffs have failed to even name Thorek in the requests, instead referring to "Healthcare Provider." The requests are not specific as evidenced by the overlap of several requests, and the requests appear to have been sent to parties and nonparties alike, with no concern for the impropriety of treating a nonparty like a party. More importantly, Plaintiffs' requests are burdensomely broad, and complying with them would

require Thorek, a nonparty, to expend immense time and resources would require immense time and resources.

Finally, PSC's requests fail to seek information during the relevant period of the outbreak and the relevant period of the Court's QPO. The outbreak involved medications that were manufactured by NECP from May through August 2012. The requests are also not limited to the timeframe set by the Court: January 2011 – November 2012.

V. REQUEST FOR COST AND FEES

PSC's overbroad and unduly burdensome requests, which seek irrelevant and privileged documents, are a clear violation of PSC's duty to take reasonable steps to avoid undue burden and expense. Fed. R. Civ. P. 45(c)(1).

Rule 45(c) allows for costs, including reasonable attorney fees, when a party has faced an undue burden or expense in objecting to a subpoenaing party who failed to take reasonable steps to ensure the subpoena would not result in an undue burden. Fed. R. Civ. P. 45(c)(1). "[G]ood faith in issuing a subpoena is not sufficient to avoid sanctions under Rule 45(c)(1) if a party has issued the subpoena in violation of the duty imposed by that Rule." *Builders Ass'n of Greater Chi.*, 2002 U.S. Dist. LEXIS 8461, 2002 WL 1008455 at *3. The Court "must determine if there has been a breach of counsel's duty to take reasonable steps to avoid imposing an undue burden or expense upon the person subject to the subpoena." *Id.* Here, because PSC has failed to take reasonable steps to avoid undue burden and expense, Thorek is entitled to reasonable costs and fees.

CONCLUSION

For the reasons stated herein, Thorek requests that the Court quash or modify the revised subpoena exhibit, in accord with Thorek's objections, and assess reasonable costs and fees against PSC and in favor of Thorek.

Respectfully submitted this 11th day of October, 2013.

By: /s/ Kip J Adams
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CERTIFICATE OF SERVICE

I hereby certify that the OBJECTIONS TO AND MOTION TO QUASH THE PLAINTIFFS' STEERING COMMITTEE'S REVISED SUBPOENA EXHIBIT has been filed

through the CM/ECF filing system of the United States District Court District of Massachusetts and all counsel of record have respectfully been notified on October 11, 2013.

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